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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,871	08/02/2001	Robert L. Rykhus JR.	687-437	5424

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EXAMINER	
THALER, MICHAEL H	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,871	RYKHUS ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,18-23,25 and 50-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,18-23,25 and 50-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the limitation in claim 18 that the stent having a fenestrated walled surface comprising molded or cut openings is gamma irradiated. Although the specification indicates that the embodiment having braided monofilaments (shown in figures 1A-1C) is both gamma irradiated ([0038]) and annealed ([0045]), the specification only indicates that the second embodiment which has molded or cut openings is annealed ([0049-0051]).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Hogan (6,569,191). Stack, in figures 17-18, discloses a tubular sheath 90 and a fenestrated walled surface comprising molded or cut openings 96, the tubular sheath 90 having an in vivo lifetime of at least 2 weeks (note the phrase "days, weeks or months" in the abstract), wherein the self-expanding stent is annealed (when the polymer is heated above its melting point as described on page 23, lines 23-30 and page 24, lines 11-18 and

page 25, lines 4-9). Stack discloses poly-L-lactide instead of polydioxanone as the bioabsorable material. However, Hogan teaches that polydioxanone may be used instead of poly-L-lactide as a bioabsorable material for stents (col. 2, lines 54-57). It would have been obvious to use polydioxanone instead of poly-L-lactide as the bioabsorable material in the Stack stent for this reason.

Claims 1-3, 8, 9, 18, 20-23, 50, 51, 57 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Cotterman et al. (2002/0153511). As to claim 1, Stack, in figures 1-6, discloses a cylindrical sleeve 10 including a latticed network formed from a plurality of monofilaments braided in an alternating braid pattern (page 8, lines 31-35) which comprise at least one biocompatible polymer (page 8, line 35 to page 9, line 2), said cylindrical sleeve having an in vivo lifetime of at least two weeks (note the phrase "days, weeks or months" in the abstract), the stent being annealed (page 26, lines 11-25) and gamma-irradiated (page 19, lines 24-28). Stack fails to disclose the amount of gamma radiation as being within the claimed range. However, Cotterman et al. teach that a stent ([0043]) should be irradiated with gamma irradiation in the amount of 39 kGy in order to sterilize it effectively ([0098]). It would have been obvious to

irradiate the Stack stent with this amount of gamma irradiation so that it too would be effectively sterilized. As to claim 18, Stack, in figures 17-18, discloses a tubular sheath 90 and a fenestrated walled surface comprising molded or cut openings 96, the stent being annealed (when the polymer is heated above its melting point as described on page 23, lines 23-30 and page 24, lines 11-18 and page 25, lines 4-9) and gamma-irradiated (page 19, lines 24-28). As to claims 9, 59 and 61, 39 kGy is in the range of approximately 50 kGy to 75kGy. As to claims 20-23, Stack fails to disclose the specific diameter claimed. However, it was well known in this art to size stents as with the specific diameter claimed so that it fits a correspondingly sized blood vessel. It would have been obvious to size the Stack stent as claimed so that it would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). As to claim 57, Stack discloses poly-L-lactide on page 17, lines 32-34.

Claims 9, 59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Schwartz et al. (6,869,938). Assuming *arguendo* that 39 kGy is not in the range of approximately 50 kGy to 75kGy, Schwartz et al. teach that a bioresorbable medical device formed of a polymer should

be irradiated with gamma irradiation in the amount of 50 kGy (5Mrad) in order to sterilize it effectively (col. 22, lines 11-29). It would have been obvious to irradiate the Stack stent with this amount of gamma irradiation so that it too would be effectively sterilized.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Schwartz et al. (6,869,938) as applied to claims 9, 59 and 61 above, and further in view of Shaolian et al. (6,261,316). Stack fails to disclose the claimed expansion force of 6 N or more. However, Shaolian et al. teach, in col. 14, lines 14-31, that the expansion force for a stent prosthesis should be as high as 8 lbs. (about 285 N) apparently in order to adequately expand the stent. It would have been obvious to provide the claimed expansion force for the Stack stent so that it too would have this advantage.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Cotterman et al. (2002/0153511) as applied to claim 18 above, and further in view of Hogan (6,569,191). Stack discloses poly-L-lactide instead of polydioxanone as the bioabsorable material. However, Hogan teaches that polydioxanone may be used instead of poly-L-lactide as a bioabsorable material for stents (col. 2, lines 54-57). It would have been obvious to use polydioxanone instead of

poly-L-lactide as the bioabsorable material in the Stack stent for this reason.

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Amstrup (5,476, 508). Stack fails to disclose a single strand shift in the braid. However, Amstrup teaches that braiding in a stent should include a single strand shift (at 12) in order to interlock the weave and apparently guarantee a stable crossing region which can accept large restoring forces (col. 4, lines 7-21). It would have been obvious to include a single strand shift in the Stack braid so that it too would have this advantage.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Thompson et al. (5,957,974). Stack fails to disclose the claimed braid angle. However, Thompson et al. teach that the braid angle for a self-expanding stent should be 60-150 and preferably 90-100 degrees (col. 7, lines 21-22) apparently in order to optimize the amount of shortening (col. 7, lines 24-35). It would have been obvious to use this braid angle in the Stack braid so that it too would have this advantage.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Turnlund et al. (5,629,077). Stack fails to disclose an under-two-over-two braid pattern. However, Turnlund et al. teach that the braid pattern for a stent should be under-two-over-two (col. 5, lines 54-56) apparently in order to obtain the desired strength of the mesh (col. 6, lines 6-9). It would have been obvious to use this braid pattern in the Stack stent so that it too would have this advantage.

Claims 52-55 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Shaolian et al. (6,261,316). Stack fails to disclose the claimed expansion force of 4, 6, 8 or 10 N or more. However, Shaolian et al. teach, in col. 14, lines 14-31, that the expansion force for a stent prosthesis should be as high as 8 lbs. (about 285 N) apparently in order to adequately expand the stent. It would have been obvious to provide the claimed expansion force for the Stack stent so that it too would have this advantage. As to the term "urethral" in line 1 of claims 52-55, the Stack stent is inherently capable of being inserted into the urethra.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (WO 91/17789) in view of Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Bolea (6,063,591). Cotterman et al. disclose sterilization using gamma irradiation or ethylene oxide [0003], but fail to disclose combining these procedures. However, Bolea teaches combining gamma irradiation with ethylene oxide for sterilization purposes (col. 8, line 65 to col. 9, line 2) apparently in order to obtain the advantage of insuring the effectiveness of the sterilization. It would have been obvious to combine these sterilization procedures during the Cotterman et al. procedure (incorporated into the Stack stent) so that it too would have this advantage.

Applicant's arguments filed Nov. 30, 2005 have been fully considered but they are not persuasive. As to claim 25, the openings in the embodiment of figures 17-18 of Stack are molded or cut as claimed. As to claim 1, the Stack stent has a lifetime of up to months as indicated in the abstract. Since the exposure of applicant's stent to 75 kGy of gamma irradiation results in the stent still having an in vivo lifetime of at least 2 weeks, the exposure of the Stack stent to only 35 or 50 kGy of gamma irradiation would inherently result in the stent still having an in vivo lifetime of at least 2 weeks.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
1/30/06

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731